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# 21 CFR PART 207 PROPOSED CHANGES CGA - GAWDA

**Medical Gas Regulation Review Public Meeting**
**FDA's White Oak Campus, Silver Spring, MD**
**December 6, 2013**

**Presenter: Tom Badstubner, GAWDA**

- **Compressed Gas Association (CGA)**
  - The CGA mission is to promote ever-improving safe, secure, and environmentally responsible manufacture, transportation, storage, transfilling, and disposal of industrial and medical gases and their containers.

- **Gases and Welding Distributors Association (GAWDA)**
  - The GAWDA mission is to promote the safe operation and economic vitality of distributors of industrial gases and related welding equipment and supplies.

- **21 CFR Part 207 needs to be changed for all pharmaceutical manufacturers**
- **For medical gases:**
  - Define “original manufacturer” and “subsequent manufacturer” since subsequent manufacturers are not explicitly certified which causes problems in the registration and listing process
  - Make provision to allow firms distributing supplier filled cylinders (filled by multiple companies) with the firm’s “Distributed By…” label to “register” and list (i.e., not through supplier)
  - Involve medical gas industry in the development of any revisions to 21 CFR 207 to assure medical gas uniqueness is addressed

## Assumptions and issues with current electronic system:

- **Certified Designated Medical Gases are listed as "Unapproved Drug". How do we get these listed as approved for:**
  - Original manufacturers
  - Subsequent manufacturers
  - Designated medical gas mixture manufacturers
- **Certified original manufacturers of designated medical gas have obtained NDA/NADA numbers.**
  - Industry assumes there is a need to update their drug listing to include NDA/NADA numbers
  - Industry assumes additional labeling information regarding indications (currently showing in Section 576(3)(A)(i) of the Act) and contraindications is not required.
- **Industry assumes the Agency will not require subsequent and mixture manufacturers to update their drug listings to include NDA/NADA numbers.**
  - If assumption is not correct, how should subsequent manufacturers address comingling of one or more original manufacturers' bulk product

## Work "around" issues with current electronic system:

- Picture of trailers or example shipping order for bulk product labels
- Multiple styles of labels for same product – must choose one
- Different physical states for same designated gas – must choose one
- Cryogenic home oxygen vessels – add label (may contradict 510(k))
- Subsequent manufacturers required to list original manufacturers on their listing
  - Only for oxygen
  - Requires subsequent manufacturer to list supplier as one of the subsequent manufacturer's facilities
- Must list "X" mL in "Y" L. Volume or mole percent not allowed
- All packages must list volume of contents in liters - even bulk containers with 14 million gaseous liters which change constantly due to vaporization
- When ownership or location changes the response time of Dun and Bradstreet typically exceeds the 5 day registration time required by the FDA (207.21), affects medical gas industry substantially more often than traditional pharma

# THANK YOU

**For questions regarding this presentation or for additional information regarding the CGA - GAWDA submitted proposals, please contact:**

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